

On design and effectiveness of a patient self-management app for reducing catheter-associated urinary tract infections

a Participatient Catheter Check case study



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1 Introduction

In the past decade, modern technology has entered the healthcare system. One form this takes is smartphone and tablet apps that can be used by patients and healthcare professionals. Such mobile health (mHealth) technologies have shown the potential to improve quality of care[1]–[3]. One way in which they can do this is by providing patients with tailored medical information[4]–[6]. Already in 2014, more than 2500 apps were available on the topic of healthcare-associated infection (HAI) prevention[7]. However, many of these applications fall short in delivering the expected benefits[7], [8]. One of the leading obstacles in mHealth effectiveness is poor usability[8].

Finding the appropriate balance between consulting a clinician or managing health problems on their own, is an important challenge for patients all over the world[9]. The increasing availability health information, particularly on the internet, is narrowing the knowledge gap between clinicians and lay people[10]. Although the patient might never have the tools to replace the role of the health care professional, the recent shift in healthcare is characterized by an increased focus on encouraging patients to take a more active interest in their overall wellbeing and recovery, and to understand the consequences of poor health later in life[1]. With the rise of interactive technology in health communication, patients can be better informed and enabled to participate in the decision making process during recovery[1], [11]–[14]. However, the promising results of digital healthcare are currently being halted by limited adoption of mHealth. Increasing the usability of mHealth apps could lead to higher adoption rates in clinical settings[8], [15].

This study is part of a larger research project pursuing to reduce catheter-associated urinary tract infections (CAUTI) by involving patients in the catheter removal process. This project hypothesizes that mHealth apps could be an instrument to reach this goal, as it is a tool to increase patient self-management[16]. The goal of this specific study is to increase the usability and thus the adoption of mHealth apps. This is investigated through prototype evaluation of the design and effectiveness of a mHealth app for reducing CAUTI that was created during this study, named the *Catheter Check*. The effect of our intervention in this paper is measured on three criteria: task completion, satisfaction, and usability. Its focus is to (i) build upon current research that identified factors causing usability problems, (ii) evaluate the application in the actual context of use, and (iii) include both patients and nursing staff in the evaluation process. The main research questions of this study are:

- 1) What are important characteristics of the context in which the mHealth app will be used?
- 2) What is the effect of the mHealth app on task completion by patients?

3) What is the effect of the mHealth app on patient satisfaction?

Based on this, we look at which recommendations can be made for reducing CAUTI using mHealth applications.

2 Background

2.1 CAUTI an current guidelines

A HAI is an infection acquired within a healthcare institution during the course of receiving treatment for other conditions. HAIs are an important problem as they are associated with an increased mortality, more adverse events, and longer hospitalisation-time[17], [18]. The most common HAI is the urinary tract infection. The majority of urinary tract infections are caused by indwelling urinary catheter (IUC) placement [15-18]. It is estimated that 20 - 30% of admitted patients receive IUCs under specific indication (**Table 1**) [19]. Almost half (46.5%) of all IUC placements are accounted by the departments of Surgery, Internal Medicine and Orthopaedics. An IUC is a breeding ground for microorganisms. Therefore, the longer the placement duration, the higher the infection risk for CAUTI [20], [21], [19]. Additionally, IUCs are mostly perceived as uncomfortable [22]–[24].

Previous studies have shown that 20 - 50% of IUCs are placed under an inappropriate indication [20] or are not timely removed [16-17]. This inappropriate indication happens more frequently in female, older and non-surgical patients [19]. Therefore, a high percentage of CAUTI could be prevented [25]. This prevention has become a priority by the European Centre for Disease Prevention and Control (ECDC) and the Rijksinstituut voor Volksgezondheid en Milieuhygiëne (RIVM) (Dutch National Institute for Public Health and the Environment). The current approach is by implementing guidelines, shifting the responsibility to nursing staff and keeping a registry [18], [26]. However, this has proved to be sub-optimal as it is time consuming, expensive, possibly not be sustainable in the long term and there is still inappropriate IUC placement[22], [27], [28]. A possible solution would be to involve the patients in the IUC removal process[21].

2.2 Current and new process of IUC decision-making

In the Netherlands all hospitals use individual guidelines for IUCs based on a national guideline[18], [20]. These guidelines include the typical pathway for the removal of the IUC (**Figure 1** and **Figure 2**): *“(1) a physician recognizes the catheter is in place, (2) the physician recognizes the catheter is no longer needed, (3) the physician writes the order to remove the catheter and (4) a nurse removes the catheter.”*[22], [29]. Patients are not actively involved in this process. In order to prevent inappropriate IUC placements or late IUC removal, we propose a new process where patients are involved in decision regarding the IUC (**Error! Reference source not found.**). Information from current guidelines could

be used increase a patient's awareness about their involvement in this process[30]. This new process would be based on the principle of self-management in which patients are empowered to recognize and monitor their symptoms and situation[31]. An mHealth app could be used to intervene in this process.

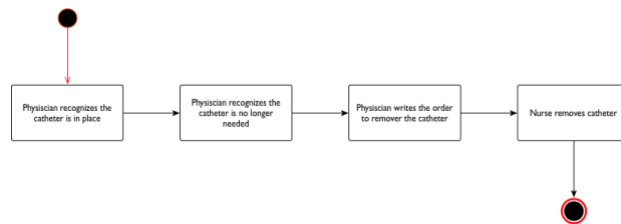


Figure 1: Old pathway of urinary catheter removal

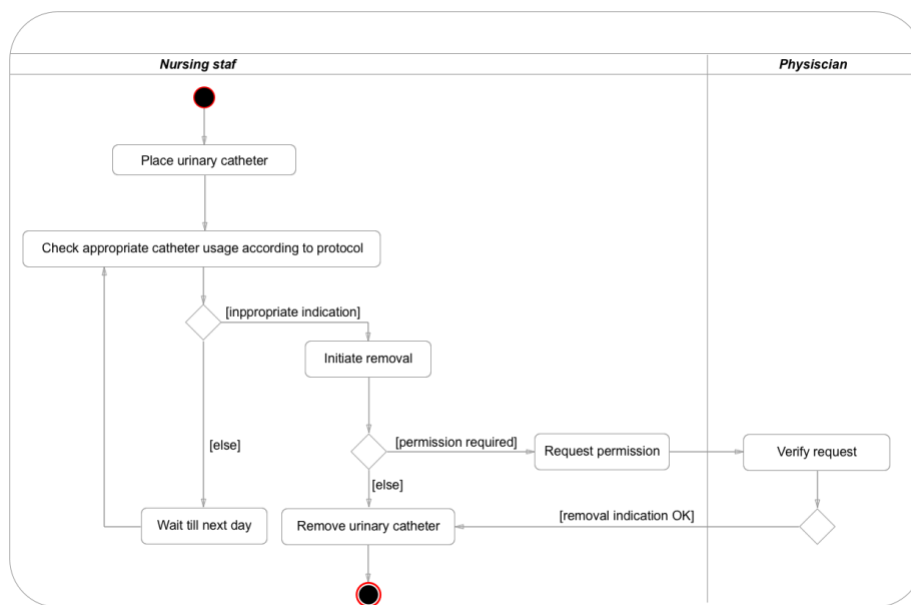


Figure 2: Activity diagram describing the various actions of the IUC removal process

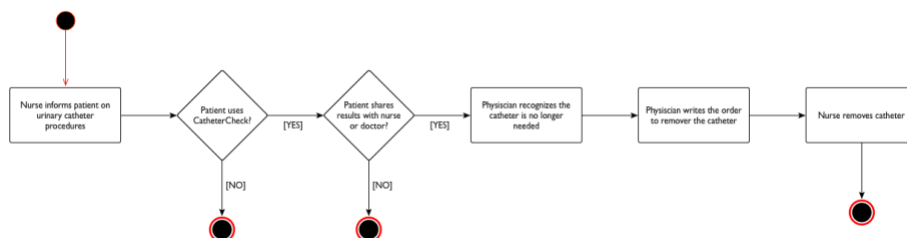


Figure 3: New pathway of urinary catheter removal New pathway of urinary catheter removal

2.3 Challenges in adoption of mHealth

Previous studies have identified several factors affecting the adoption of mHealth[1], [8]: applications are insufficiently integrated in the clinical setting; offered features do not match the users' needs; too little functionality; timing in illness trajectory is not optimal; presumptions about the patient role and health-literacy do not match practice. Therefore, design and timing have a central role in the adoption of mHealth. An effective mHealth app requires understanding of the perspectives and values on the different users. In this case, the users are the patients and healthcare professionals. Additionally, development of mHealth tools requires close collaboration with software companies or other external partners involved in developing technology for mHealth[32]. A widely-used method for gathering data on the context of use is Contextual Inquiry[33]. Contextual Inquiry combines interviews and field observations to gather data about the intended users and the environment in which the application will be used. This method can help to gain a better understanding of: the IUC process in practice, patient and nursing staff needs, and how the *Catheter Check* app should be adapted to match to that.

3 Product

3.1 The *Catheter Check* mHealth app

The *Participatient Catheter Check* is a mHealth app assisting patients to take an active role in the IUC process. It offers an interactive checklist that patients can use to monitor whether their ICU is appropriate in their situation (**Figure 4**). It also includes a decision support tool according to a flowchart decision algorithm (**Figure 5**). This decision support tool displays a short information module followed by a questionnaire about the IUC. Based on the answers, the *Catheter Check* generates three types of results: appropriate, inappropriate and unknown ICU placement (**Figure 6 & Figure 7**). Following, patients can discuss these results with their healthcare professional. In the end, the healthcare professional can

decide whether ICU removal is indicated. Using this method, the *Catheter Check* can prove to be a tool leading to less inappropriate IUC placements or late IUC removal. The starting-point for this research was a functional mock-up prototype created during a hackathon, outside the actual context of use. Considering the background of the problem, the first requirements for the *Catheter Check* are:

- The system adheres to evidence-based guidelines for catheter related infection prevention
- The system is suitable for older adults
- The information and services are designed to support self-management
- Enables patients to participate in healthcare decision making process

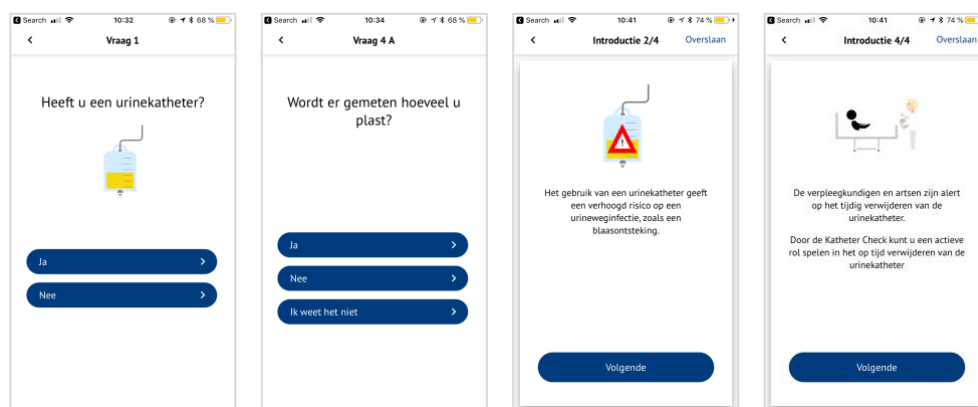


Figure 4: Screenshots of *Catheter Check* application at the end of this study. From left to right: (a) question: do you have a urinary catheter? (b) question: do you need a urinary catheter to measure how much you urinate?

(c) introduction text: warning about increased infection risk. (d) introduction text: explain role of doctors and nursing staff and what the *Catheter Check* can be used for.

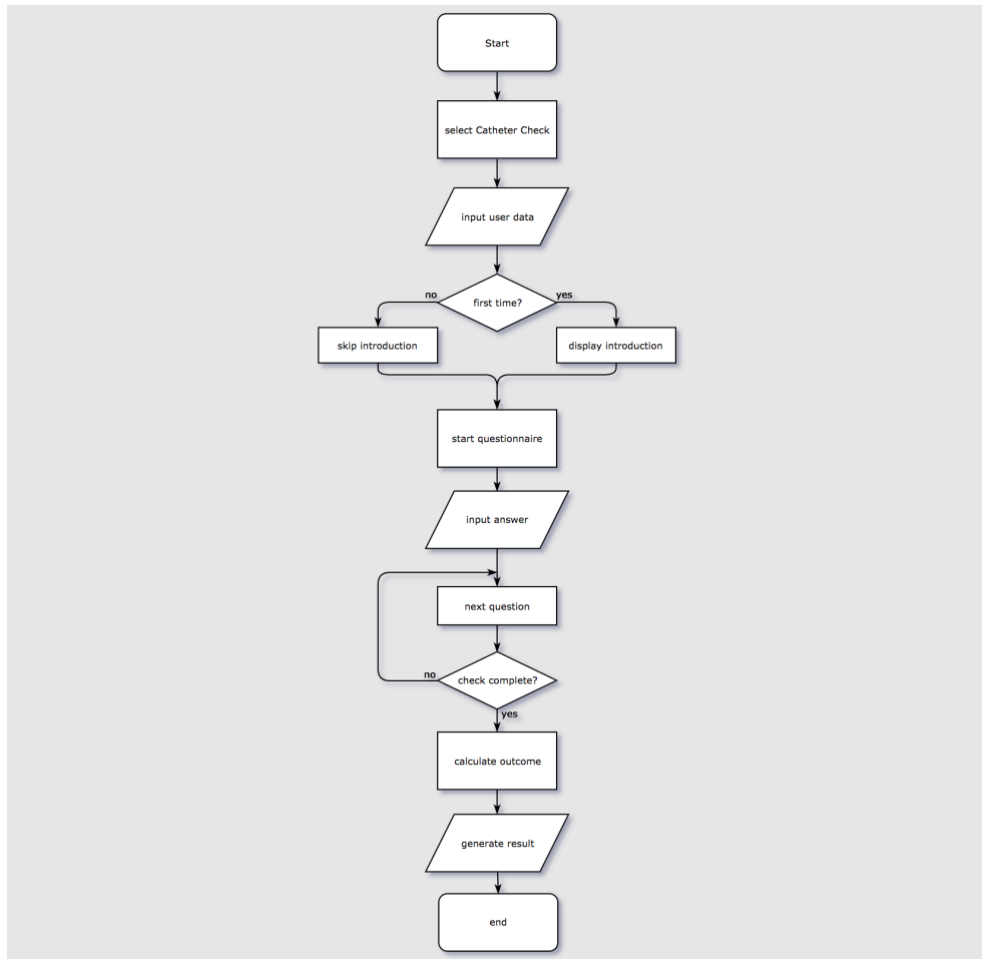


Figure 5: Flowchart for *Catheter Check* decision support

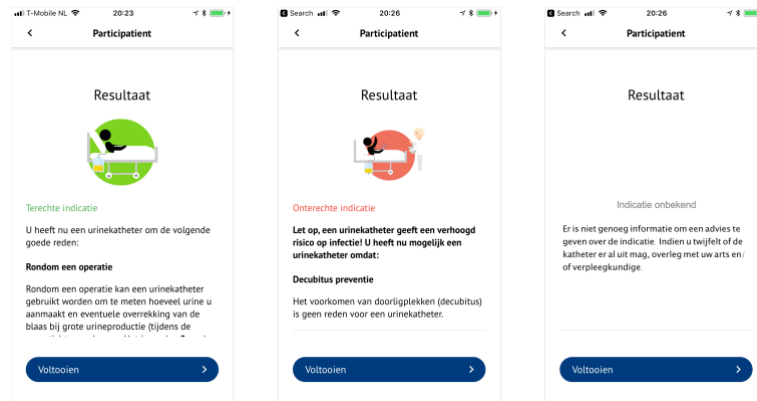


Figure 6: Three types of result of the *Catheter Check*. From left to right: (a) appropriate IUC indication (b) inappropriate IUC indication. (c) unknown indication due to lack of information

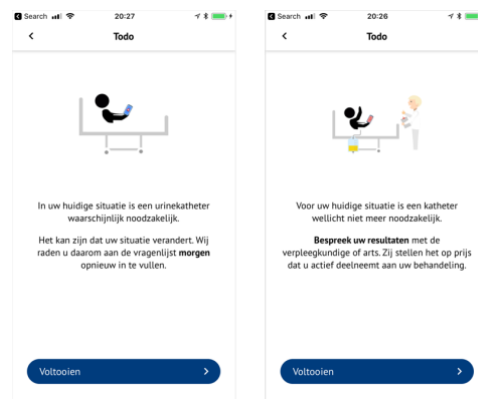


Figure 7: Advice following the results page after appropriate IUC indication (left) and inappropriate IUC indication (right)

4 Research questions and methods

Methods for improving the usability of an mHealth application generally involve a process of analysing the context, conceptualisation & creation of prototype, evaluation, followed by improvement of the prototype[32]. Oftentimes this process is repeated until the desired results are achieved, or until resources run out. An overview of the procedures used in this study can be found in **Figure 8**.

During three months from April till June 2017, the *Catheter Check* mHealth app was developed and evaluated in a four-phase mixed method usability study. In this period, 25 male and female patients with IUCs were recruited from two surgical departments at the Leiden University Medical Centre (LUMC) hospital. Each phase involved evaluation of a *Catheter Check* prototype, followed by an iteration where the prototype was improved based on the evaluations, resulting in new prototypes for the next evaluation phase. New features were evaluated in an A/B testing. The evaluations studied the effect of prototype improvements on effectiveness along with the effect on task completion, satisfaction and usability. Additionally, patients and staff members were interviewed to create a rich picture of the triadic interaction between patient, professional, and tool through contextual inquiry. In particular, this study includes three type of evaluations:

- (a) Contextual inquiry
- (b) Task completion & usability metrics
- (c) Qualitative description of usability issues

An overview of the instruments used for data analysis can be found in **Table 4**). The interview transcriptions were used to identify the frequency of reported usability issues.

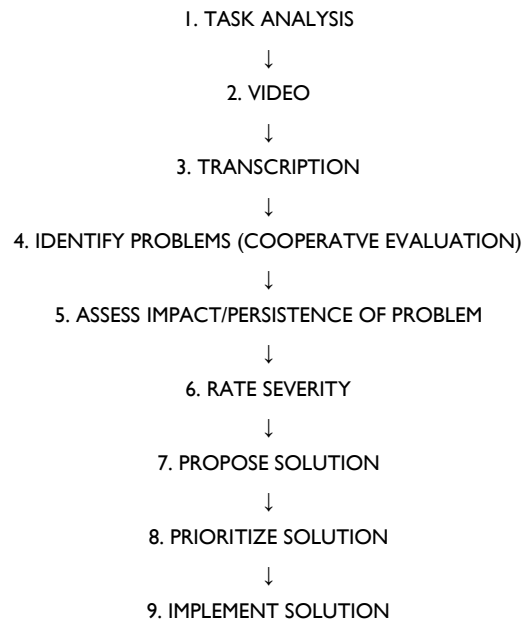


Figure 8: Usability Analysis Procedure

4.1 Theory behind *Catheter Check* mHealth app

The application model for the *Catheter Check* is based on research from the past 20 years on the requirements of successful mHealth tools for CAUTI prevention to be used by patients[22], [32], [34]–[36], in addition to the effect on task completion, satisfaction and usability. A unified list of appropriate IUC indications was created based on guidelines currently used by staff members in the LUMC[18], [37]. This list was incorporated into the *Catheter Check*, and a set of heuristics was used to improve the prototypes during the three iterations (see **Table 1** & **Table 2**). To provide the overall model for the intervention, the theoretical model of Stanford’s Chronic Disease Self-management program[38] was adapted and extended with findings from the literature, with a focus on mHealth usability. The theoretical concepts of awareness, self-monitoring, and self-management were extended with the concepts of engagement[39]–[42], mHealth interaction and elements of shared decision making[43].

The first usability specification was based on healthcare protocols combined with existing literature on health behaviour change, health information design and interactive health applications. Content was devised based on existing guidelines[18], [37] and expert evaluation of the researchers involved in this study (**Figure 9**). Interaction elements were selected based on Wildenbos’ framework for evaluating mHealth[44], and their effect on patient experience was evaluated during the usability research. A

combination of traditional usability methods with analysis of user experience was used to evaluate the implementation of this design. **Table 3** shows an overview of the evaluations and the measurement instruments used.

4.2 Software development

Development of the *Catheter Check* application was done in collaboration with a software company[45]. Based on the first usability specification created as part of this study, the company created the design for the initial prototype (**Figure 9**), according to iOS/android standards. This prototype was evaluated in a preliminary field test with three medical students to ensure baseline functionality.

The evaluations included in this study were performed during three stages of iterative development. During each iteration the usability specifications were updated and the prototype was adjusted accordingly. In order to explore alternative interface designs, while limiting the costs of development, mock-ups designed by the principal researcher were used for AB-testing to represent suggested prototype improvements. Mock-ups (A) were compared to the functional prototype (B) developed in parallel based on the evolving requirements during the study (**Figure 10**).

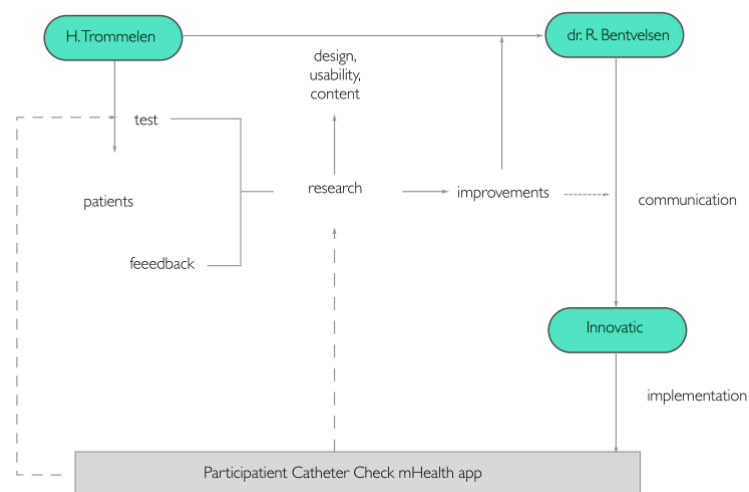


Figure 9: Collaboration diagram for development and evaluation activities

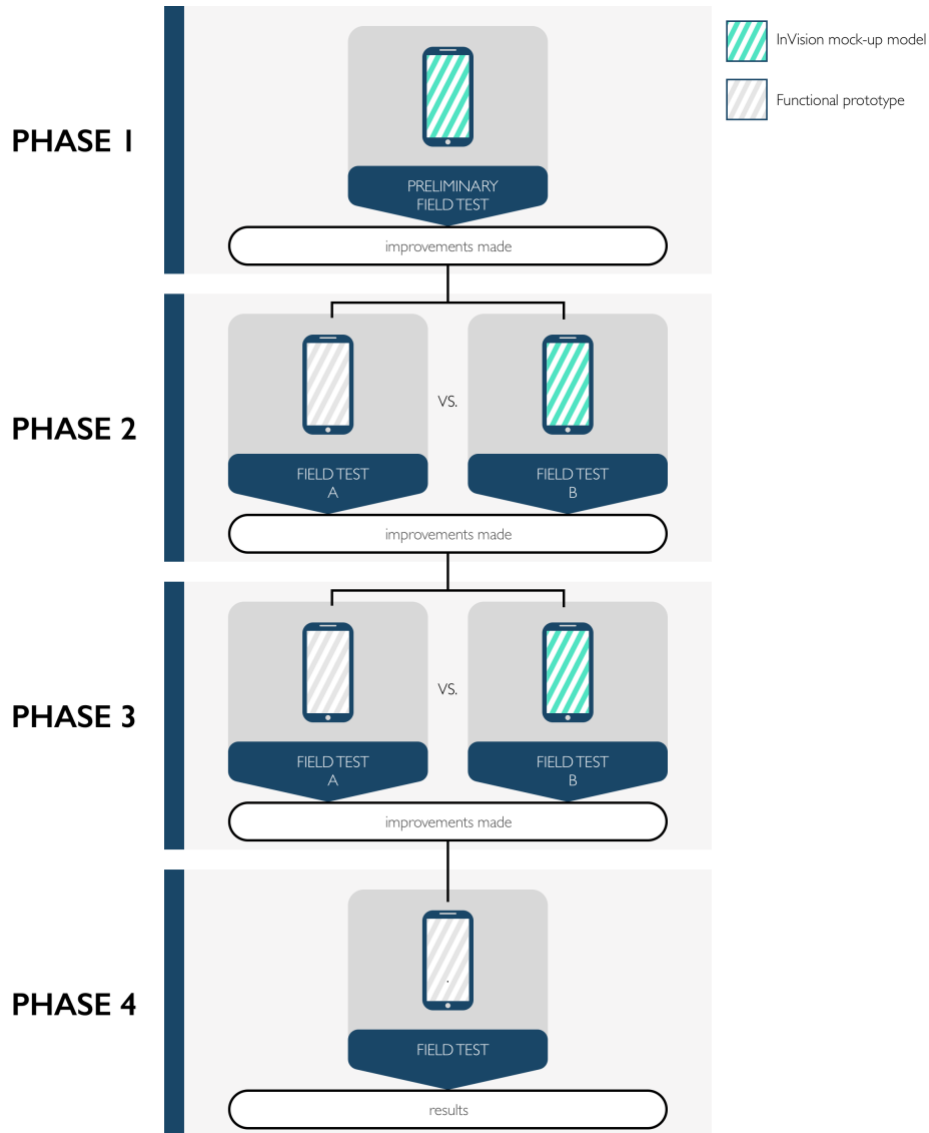


Figure 10: Prototypes used during four phases of development

4.3 Contextual inquiry

Usability is defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use”[46]. In order to improve the uptake and impact of our *Catheter Check* application, the needs and values of the different stakeholders involved must be understood[32]. A widely-used method for gathering data on the context of use is Contextual Inquiry[32]. We applied this method to gather gain a better

understanding of: the IUC process in practice, patient and nursing staff needs, and how the *Catheter Check* app should be adapted to match to that context. Contextual Inquiry combines interviews and field observations to gather data about the intended users and the environment in which the application will be used. Findings are based on data gathered from the intended users through interviews, field test observations and questionnaires. Interviews with patients and nursing staff were conducted on-site at the bedside, or in a separate consultation room, according to their preference. Nursing staff members were asked about their experience with the current CAUTI related health care delivery. Interviews with patients included questions on mHealth experience and IUC usage (**Appendix 3**). Additionally, data from literature was used to describe the values of the infection prevention organizations. The insights obtained through Contextual Inquiry set the base criteria for deciding what the mHealth app should do and how it should be structured.

4.4 Usability testing

As soon as development of working prototypes for each phase was finalized, usability tests were conducted with a minimum sample size of 5 patients during each phase to ensure meaningful identification of problems[47]. See **Appendix 3** for a detailed description of prototype evaluation procedures. A cooperative evaluation approach was used to detect usability problems and to improve the user interface specification. This evaluation method is known to provide valuable information on the interface design, but also helps understanding how patients will ultimately use the *Catheter Check* application in the hospital setting and gaining insight in their perspective on potential problems and solutions. For the evaluation of the Participatient application this task was to complete the *Catheter Check* module. The think-aloud protocol was used to actively involve participants in the evaluation process, meaning participants were asked to verbalize their thoughts while performing tasks. This resulted in verbal protocols that were analysed to evaluate the interface design.

Previous studies have shown that various issues remained undetected due to false assumptions about technology available to patients[14], [48], [49]. Therefore, participants were asked to use their own mobile device, in order to create a testing environment that equals the actual context of use[49]. Semi-structured interview and Likert-scale questions were used to obtain information regarding the satisfaction and usability of specific features and the *Catheter Check* module.

New features are evaluated in phases 2 and 3 with the A/B-testing method[50]. A prototype with a new feature (A) is compared with a prototype without the new feature (B). In order to analyse the usability of these new features, this evaluation uses a randomized cross-over design in phases 2 and 3.

This allows for within-participant comparisons of the prototype features, as each patient serves as their own control. Participants evaluate both prototypes consecutively but in a randomly assigned order (Figure 11). This randomization serves to minimize the effect that the order of testing may have on the reported outcomes.

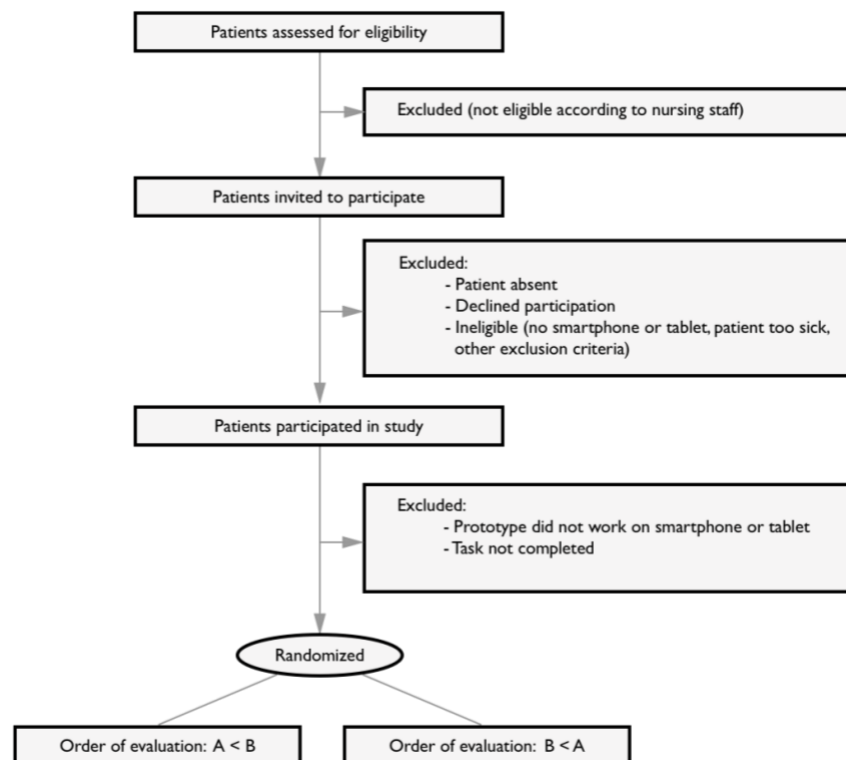


Figure 11: Usability Study Design

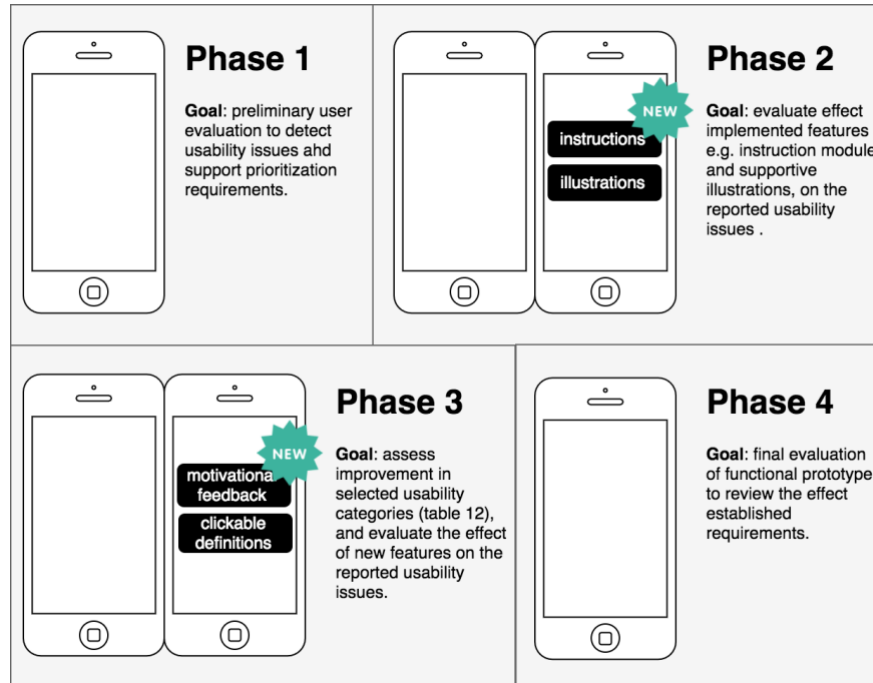


Figure 12: Iterative prototype evaluation, phase 1-4.

4.4.1 Outcome measures

In this preliminary pilot study, the purpose of usability research is to determine the directions design should take; not yet to produce a completely functional end product. Within human computer interaction, task completion is a very commonly used measure. So in this case, the recommended usability measure is user success rate[47], or task completion rate, which is defined as the percentage of tasks that users complete correctly. Successful task completion was defined by the percentage of participants who autonomously completed the *Catheter Check* from [start] to [end] (**Figure 13**).

In our case, a new task is introduced into the clinical setting. The task assigned to the participants is to complete the *Catheter Check* on their own mobile devices. The *Catheter Check* task completion rate signifies the ease of use of this application and its suitability for the user group. The target level for task completion rate is set at 100%. With this, we establish several of the conditions essential for task completion.

4.5 Study procedures

Field test study procedures

The staff members from the respective departments were asked to identify patients using a smartphone or tablet. Patients were included based on the following inclusion criteria: possession of smartphone or tablet, whether they

had previously used an IUC, and whether they were not too sick to participate. Eligible patients were asked face-to-face to participate in the research.

Eligible patients received a short introduction of the think-aloud method and were instructed to complete the *Catheter Check* app. Additionally, the participant sessions were moderated on predetermined usability items through concurrent probing (**Table 11**). As part of the iterative process, users were observed while performing a task using a cooperative evaluation approach. The goal was to determine whether the design is successful or not, should be adopted so that the possibility of negative results are minimized from the start through formative evaluation. The interactions were captured on video. At the end of the evaluation session, participants filled out the System Usability Scale (SUS), extended with an app-specific questionnaire to assess the perceived impact of the app on the user's knowledge, attitudes, intentions to change as well as the likelihood of actual change in the target behaviour. The set of questions included was the functionality subset from Mobile Application Rating Scale (MARS) and included [51]. Criteria for excluding the data of the interviews in the results were if the data contained too little information due to interruption of the interview. In total 2 interviews were excluded from the results. In total, the results of 19 patient interviews were used for this study.

4.6 Analysis

The participants were clustered in four age groups: respectively younger than 18, 18-45, 46-60, 61-75 and older than 75. This specific clustering was chosen because of the increased risk on urinary tract infections that exists in patients over 60. Furthermore, due to the age restriction for patients admitted to the transplantation department, it is expected that the group of participants interviewed at the transplantation department will fall in lower age categories. The type of mobile device, internet usage and previous experience with health related apps were used to categorize experienced and less experienced users.

Outcomes of usability tests were used for requirement specification. Firstly, the requirements were reviewed and prioritized using the MoSCoW technique[33]. It classifies requirements into four priority groups: "Must have", "Should have", "Could have" and "Won't have" (**Table 5**). The "Must have" category describes requirements without which the system will be unworkable and useless. Therefore, requirements for this application were assigned to the "Must have" category. Secondly, the severity of the usability problems was determined according to: (a) their effect on module completion, and (b) correct self-administration of the indication. Issues were categorized as 'severe' when task completion was hindered. Lastly, solutions were proposed for the most important usability problems were matched with potential solutions (

Table 6).

5 Results and Evaluation

5.1 Contextual Inquiry

Semi-structured interviews with 6 nursing staff members and 14 patients were used to create an overview of the stakeholder needs and to specify the critical issues for design and implementation (**Table 10**). **Figure 15** provides a conceptual model of the patient journey and illustrates the context of use of the *Catheter Check* for the two most important actors affected by this intervention: patients and nursing staff. It illustrates the various touch points that are relevant to support this technology and their relation to the information space. CI made apparent that, in this case, health information can be provided directly, through conversations or indirectly, through a document (e.g. questionnaires; checklist). A nurse can interact with a patient by providing instructions, answering questions, providing practical information, conducting a questionnaire, performing a check-up, and providing other types of support (**Figure 14**).

During the interviews, the nursing staff mentioned that, overall patients are acceptant to the necessity of IUC usage. Even though many patients reportedly find IUC usage uncomfortable and would prefer removal, catheterized patients in this department do not typically ask questions about the IUC procedure. Interviews also revealed that questions asked by patients were most commonly about practical information. Interviews with patients revealed that, although all patients were smartphone users, the number of mHealth users was very limited. Only 2 patients stated they have used some type of mobile application for health related purposes, of which only 1 used mHealth for self-monitoring. This indicates that an effective implementation includes two steps: 1) adoption of self-monitoring behaviour and 2) increased patient-carer communication. The low amount of mHealth experience among smartphone users confirms that special attention needs to be paid to addressing the reasons for not using mHealth.

Analysis of the interaction pathway showed that the effectiveness of the intervention is driven by two main decision making moments: 1) the patients' decision to participate in self-monitoring their IUC usage, e.g. downloading the app and completing the *Catheter Check* module on a daily basis, and 2) the patient decision to ask the doctor or nurse for help based on the *Catheter Check* module, e.g. discusses their results with a medical professional or asks questions.

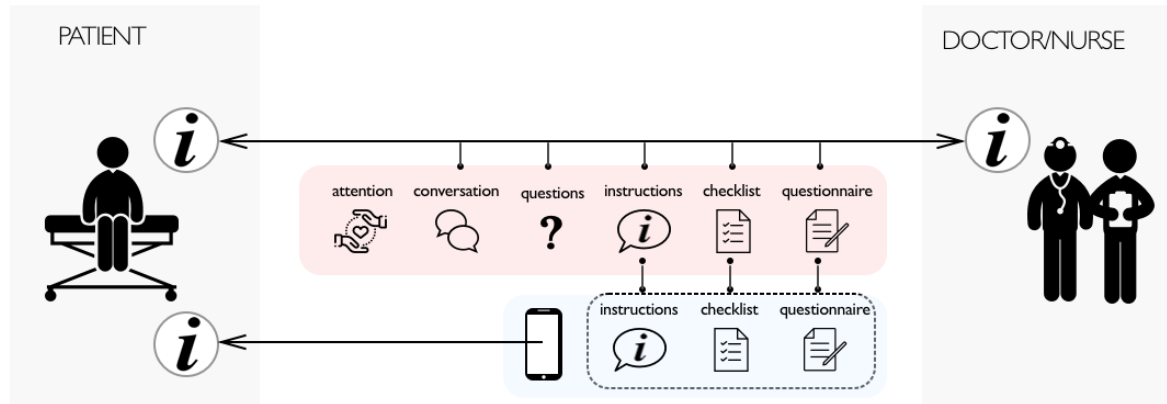


Figure 14: Interactions between patient and nursing staff

5.2 Usability outcomes

Demographic information

There are 19 patients involved in this usability evaluation study. All were aged between 18 and 75 years old. The most occurring age group was 18 – 45 (42%), followed by 46 – 60 (32%), and 61 – 75 (21%) year olds. The gender distribution was 26% male and 68% female. With regard to age-related perceptual problems, 4 patients reported visual impairments, of which half were related to the hospital stay (e.g. surgery or other treatment).

Task completion and satisfaction

We analysed all participants who achieved successful task completion or terminated usage of the application before task completion was achieved. In total 19 patients evaluated the application at four stages of development. Data from two participants was incomplete due to interruptions and therefore excluded from analysis. After the first iteration, all participants successfully completed the task. The outcomes of the task analysis can be found in **Table 7**. Among all patients who evaluated the *Catheter Check*, successful task completion was achieved in 77%. Hence, after the first iteration all participants successfully completed the application. No significant difference between SUS-scores was found between iterations. The average SUS-scores for prototype 2b and prototype 3a were respectively 28 and 31. This means that the differences in design did not affect overall usability.

5.3 Qualitative description of usability issues

Prototype 1a

The usability issues reported during the first prototype evaluation are listed in **Table 8**. In total 19 usability issues were reported. Three participants were not able to complete the task. One participant was unable to read the text due to small font size and ended the task at the intro screen. This participant had no previous visual impairment problems. Another participant was unable to initiate the *Catheter Check* module because the interface view was limited on their device. The third cause of untimely ending the task was because the ‘show results’ button did not work. The other participants reported issues related to interpretation, language, buttons that did not work. The interpretation issues were limited to a few questions: 1, 4, 6A and 8, of which question 4 and 6A were most problematic. Lastly, we also found that, without instructions, none of the participants utilized the features for extra information such as: ‘more info’ and the highlighted medical definition.

Improvements made. It was proposed to improve the phrasing of question four by splitting it into two questions. And it was proposed to improve question six by eliminating the denial. See

Problems with version 1b

All 8 participants successfully completed the task. The most frequently reported usability issues were related to the readability of the text and the use of language. The majority of the users found the text too small. Furthermore, two participants required additional instructions to continue to the result screen. Examples of other usability issues are:

- too much information in the result screen
- purpose of the overview screen is unclear
- the answers are not saved after closing the questionnaire
- you can’t go back if you answered a question wrong (overview screen)

Problems with version 2a

The majority of the usability issues in version 2a were related to the interpretation button labels. The button labels ‘to do’ and ‘read instructions’ did not afford to continue to the next page. Other issues were related to the nature of the prototype. Because version 2a was an InVision mock-up model, the buttons on the bottom of the screen were not visible on every device.

Additionally, the information module elicited some issues on the satisfaction with the information content. The following quote illustrates the need for personalized information:

“Straight off first mentioning the risks is kind of intense. Maybe it’s better to first mention that you do not always have a choice, and what the consequences of that could be. That is just a little less heavy.” (Participant 4, female)

Additionally, the response of another participant showed how previous knowledge can affect the apparent relevance of the information:

“Yes that might be the case, but you can also have a urinary tract infection without using a catheter, when you have a small urethra or bladder stones, you also have a high risk.” (Participant 8, female)

Overall the participants responded positively to the features added in version 2a.

The additional explanation and images in version 2a were perceived as valuable.

Participants expressed the images:

- increased awareness
- made the information more clear
- increased ease of use

Evaluation

We evaluated the Participatient *Catheter Check* mHealth app. The three key stakeholders in this project are: patients, nursing staff and infection prevention organisations. In total 19 patients evaluated the application at four stages of development. A total of 76 usability issues were reported and 20 suggestions for improvement were given. The most frequently occurring usability factors were respectively ‘effective use of language’, ‘readability’ and ‘navigation’.

Most users found that the readability of the text was sufficiently improved in prototype 2a, but some readability issues still remained. In relation to motivation, one patient mentioned the following in “Depends on the situation, when I have more pain or when more things are going on, I would probably be more likely to use the app.” Overall, the design, content and features of version 2a were perceived better than those of version 1b. An overview of the proposed solutions can be found in **Table 6**.

Based on design heuristics and literature on and decision aids, the prototype was improved with several features: risk information, visualizations, feedback, motivational cues, and improved navigation. Answers to the questionnaire showed that most patients found that using the application positively affected knowledge on infection risks and awareness on the importance on timely IUC removal. Information needs retrieved from the interviews are listed in Table 7 (predisposing factors).

6 Conclusion and discussion

In this paper, we have presented the design and evaluation of a digital intervention enabling catheterized patients to use in-hospital CAUTI prevention protocols for self-monitoring purposes. We have introduced a new mobile application module, named the *Catheter Check*, which functions as an IUC monitoring tool that can be controlled through a questionnaire-like interface. The *Catheter Check* was hypothesized as an additional pathway to assess and monitor appropriate IUC usage. We used task analysis to translate this potential pathway into a predefined task. This pathway was confirmed during user evaluation. Successful task completion was achieved during task analysis, suggesting that this could be an additional pathway for assessment of appropriate IUC usage.

The strengths of this study are the inclusion of multiple stakeholders in early stage development, achieving successful task completion (100%) in the last two iterations, the analysis of the contextual inquiry, and the use of user feedback and heuristics to improve prototypes for the next iteration. Achieving successful task completion shows that the hypothesized pathway is possible and that monitoring CAUTI status can also be performed by patients. This indicates that the *Catheter Check* has the potential to become an integral part of solving the CAUTI problem, without increasing pressure on medical staff or increased usage of current resources. The number of usability issues found in the several prototypes, shows that many deficiencies are present that could have unintended consequences and errors. The results are in line with earlier evidence that suggests that deficient interface design may contribute to causing unsafe workarounds which may lead to unintended consequences and errors affecting the IUC removal pathway[8]. When left unattended, these deficiencies may contribute to lower satisfaction and lower rate in task completion. Additionally, interviews with users showed that most users have no previous experience with mHealth technology because they do not perceive it as useful or, simply because they have no interest in using mHealth technology. Though, reasons for this limited perceived usefulness varied widely and could not be attributed to a single factor. Overall, it showed to be relatively easy to use and the minimal usability levels were achieved, suggesting that the *Catheter Check* has the potential to become a useful self-management tool for catheterized patients.

Limitations of this study include the within-participant comparison and the use of SUS-scores. Firstly, reported outcomes from participants that serve as their own controls may improve for reasons unrelated to the mHealth app. Due to overlapping processes of development and evaluation in relation to the short time window catheterized patients were available for field tests, within-participant comparison was limited to comparison of the functional prototype to the mock-up. Due to the limitations of the InVision software, the mock-up prototypes provided a slightly different experience from the functional prototypes. Some of the reported usability issues in the mock-up prototypes were caused by these limitations and affected the comparison with the functional prototype. Secondly, during every field test evaluation, SUS-scores were used to evaluate overall satisfaction. Though the

System Usability Scale provided some useful information that could be used for future comparison, it did not assist in improvement of the prototypes. The other measures used deemed far more suitable for this. For an early phase study such as this one, it might be worth to limit its use to the first and the last iteration. Lastly, as patients included in this study were selected based on their usage of smart devices, the sample is skewed in the direction of experienced technology users.

Generally, a lot of information is available online, but a large portion is also inaccessible or interpretation is too difficult for patients. Our findings contribute to previous research indicating that interactive technologies enable participation in the decision making process during recovery[1], [11]–[14]. We demonstrated that the use of the CAUTI web intervention increases the number of touch points for IUC removal. Moreover, we showed that catheterized patients are able to use and interpret information that was previously only available for healthcare professionals. The results of this study confirm the hypothesis that the design of a CAUTI web intervention has the potential to positively affect the timely removal of IUCs, and provides directions for future research in user characteristics, cost effectiveness and process organisation. By outlining an additional pathway and the identification of areas of improvement, this study has brought us a little bit closer to the development of a solution that reduces pressure on the health care professionals, and therefore is less resource intensive than current solutions, such as monitoring IUC use and CAUTI rates by staff only to inform and sustain IUC-related interventions.[22] The *Catheter Check* has the potential to become an integral part of minimizing the CAUTI problem.

It is known that timely removal of IUCs can be problematic, especially in situations where caretakers have to deal with multiple indications for placement change over time. Moreover, the focus of this study is in line with the desire of the European Commission to improve development programmes in the areas of empowering patients, and developing a culture of learning from mistakes[21], [52]. Currently, no hospitals involve patients in the IUC removal process. This preliminary pilot study the first phase of larger study where other aspects of this web application will be researched more thoroughly, such as adoption rate and effect on IUC removal rate. It provides a small part of the research required for the development of digital health solutions supporting CAUTI patients. An RCT and/or cost analysis is necessary to establish the benefit of further development of this solution. Ultimately, we hope to lower the number of complications and signs and symptoms for CAUTI patients using this web based intervention

In conclusion, this intervention has the potential to tackle the problems related to one of the most common HAI: the urinary tract infection. The CAUTI web intervention has the potential to improve appropriate indwelling IUC placement. The purpose of this research was to provide the first few steps in establishing the requirements of a web application. This research provides a small part of the research required for the development of digital health solutions supporting CAUTI patients. It contributes to the current evidence with new insights on

usability characteristics, context of use and study design. Additionally, it provides directions for future research in user characteristics, cost effectiveness and process organisation. The results of this study will be used to further improve the adoption of mHealth apps.

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Abbreviations

CAUTI	catheter associated urinary tract infection
CeHRes	Center for eHealth Research and Disease Management
CI	contextual inquiry
ECDC	European Centre for Disease Prevention and Control
HAI	healthcare associated infection
HIT	health information technology
IUC	Indwelling urinary catheter
mHealth	mobile health
PICO	Population Intervention Comparison Outcome
RIVM	Dutch National Institute for Public Health and the Environment
SUS	System Usability Scale
UTI	urinary tract infection
WIP	Werkgroep Infectie Preventie (this working group was discontinued in 2017)

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APPENDIX 3: EVALUATIONS

Instructions for user evaluations (in Dutch)

Concurrent Probing Items

Contextual Inquiry

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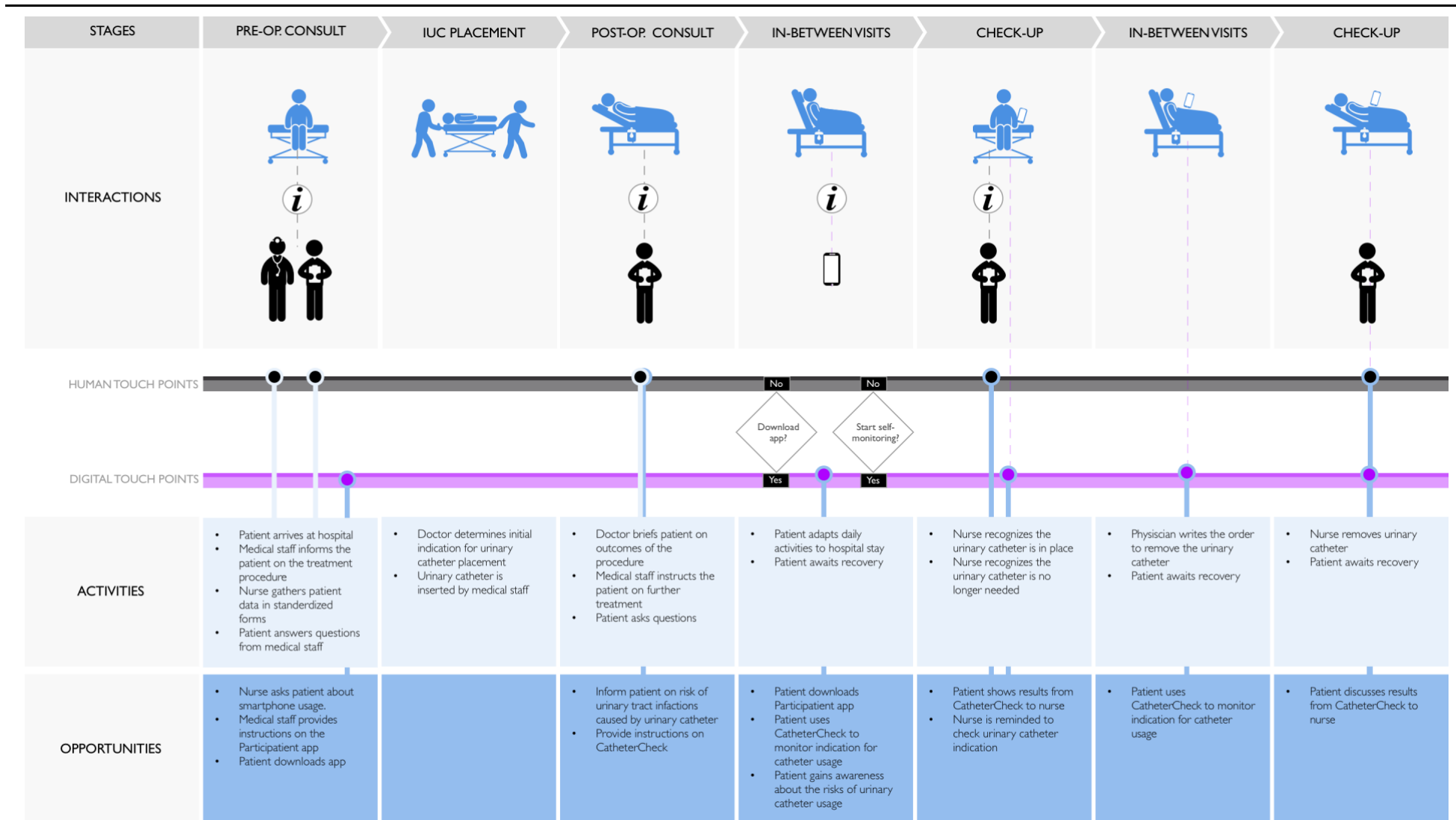


Figure 15: Intervention mapping

Adaptations in *Catheter Check* questions during iterations

PRELIMINARY TEST		PHASE 1		PHASE 2		PHASE 3		PHASE 4	
1	Heeft u een urinekatheter?	1	Heeft u een urinekatheter?	1	Heeft u een urinekatheter?	1	Heeft u een urinekatheter?	1	Heeft u een urinekatheter?
		2	Hoe lang?	2	Hoe lang heeft u een urinekatheter?	2	Sinds wanneer heeft u een katheter?		Hoe lang heeft u een urinekatheter?
2	Ik heb een operatie gehad en vanwege de operatie is een katheter geplaatst.	3	Heeft u een operatie gehad?	3	Heeft u een operatie gehad?	3	Heeft u een operatie gehad?	3	Heeft u een operatie gehad?
3	Ik heb een katheter... ... om te meten hoeveel ik plas en ik kan niet op verzoek regelmatig zelf plassen.	4	Wordt er gemeten hoeveel u plast en kunt u niet op verzoek regelmatig zelf plassen?	4A	Wordt er gemeten hoeveel u plast?	4A	Wordt er gemeten hoeveel u plast?	4A	Wordt er gemeten hoeveel u plast?
				4B	Kunt u zelfstandig urine verzamelen?	4B	Kunt u zelfstandig urine verzamelen voor meting?	4B	Kunt u zelf urine verzamelen om bij te houden hoeveel u plast?
				4C	Wordt de urineproductie gemeten omdat u ernstig ziek bent?				
4A	Ik heb een katheter... ... vanwege incontinentieproblemen.	5A	Heeft u incontinentieproblemen?	5A	Heeft u incontinentieproblemen?	5A	Heeft u incontinentieproblemen?	5A	Heeft u incontinentieproblemen?
4B	Heeft u een open wond in het gebied van uw stuitbeen/anus?	5B	Heeft u een open wond in het gebied van uw stuitbeen/anus?	5B	Heeft u een open wond in het gebied van uw stuitbeen/anus?	5B	Heeft u een open wond in het gebied van uw stuitbeen/anus?	5B	Heeft u een open wond in het gebied van uw stuitbeen/anus?
5	Ik heb een katheter... ... omdat het niet lukt om leeg te plassen of omdat ik last heb van nadruppelen.	6A	Lukt het u niet lukt om leeg te plassen?	6A	Lukt het u niet lukt om leeg te plassen?	6A	Lukt het om uw blaas volledig leeg te plassen?	6A	Lukt het om uw blaas volledig leeg te plassen?
		6B	Heeft u last van nadruppelen?	6B	Heeft u last van nadruppelen?	6B	Heeft u last van nadruppelen?	6B	Heeft u last van nadruppelen?
6	Ik heb een katheter... ...ter preventie van doorligplekken.	7	Ligt u veel op bed en heeft u risico op doorligplekken?	7	Ligt u veel op bed en heeft u risico op doorligplekken?	7	Ligt u veel op bed en heeft u risico op doorligplekken?	7	Ligt u veel op bed en heeft u risico op doorligplekken?
7	Ik heb een katheter... ...omdat er een residubepaling moet worden gedaan.	8	Heeft u een katheter omdat er een meting van het volledig leegplassen van de blaas (residubepaling) moet worden gedaan?	8	Heeft u een katheter omdat er een meting van het volledig leegplassen van de blaas (residubepaling) moet worden gedaan?	8	Heeft u een katheter omdat er een meting van het volledig leegplassen van de blaas (residubepaling) moet worden gedaan?	8	Heeft u een katheter omdat er een meting van het volledig leegplassen van de blaas (residubepaling) moet worden gedaan?

Figure 16: Adaptations in *Catheter Check* questions during iterations

Phase 1 - Step A

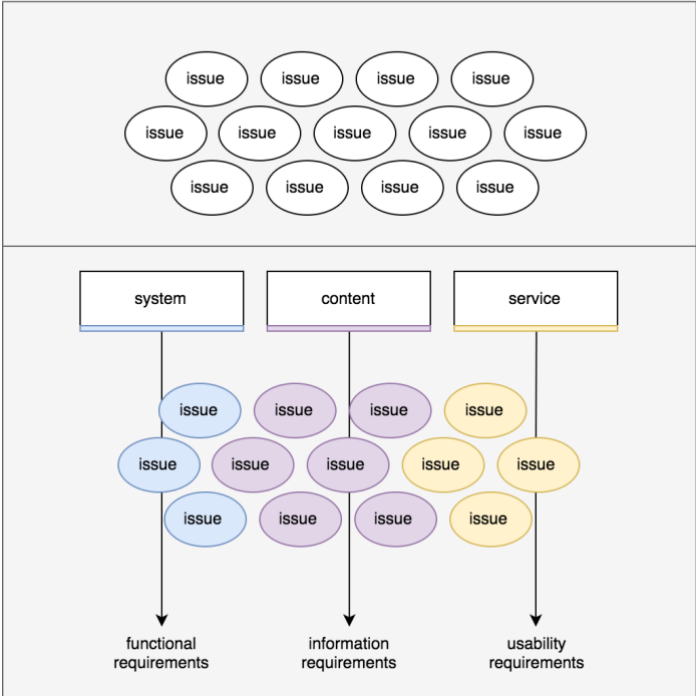


Figure 17: Phase 1 - step a: categorization of observed usability problems sets the basis for requirements gathering.

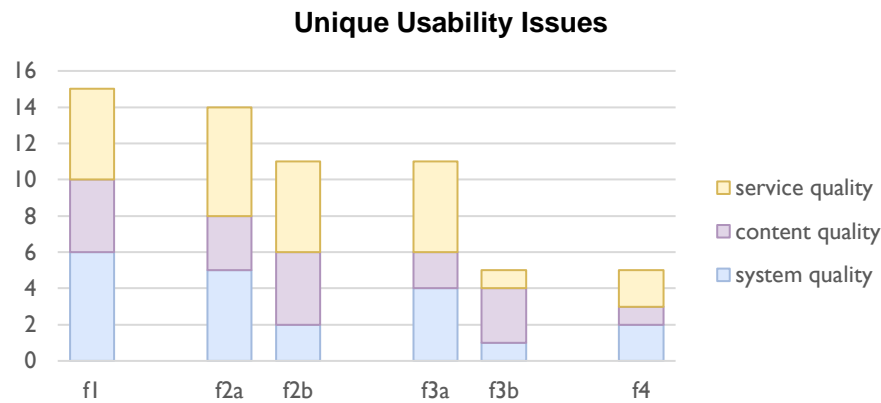


Figure 18: Number of unique usability issues for each prototyp

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2.1 Introduction

Table 1: Indications for urinary catheter use

Indication	Code*	2009 Centers for Disease Control and Prevention guideline	Guidelines
Appropriate	C-a1	Acute urinary retention	RICAT 2017, PREZIES 2017
		Bladder outlet obstruction	RICAT 2017, PREZIES 2017
		Neurogene (overloop) blaas	PREZIES 2017
	C-a2	Accurate measurements of urinary output in critically ill patients required for treatment	RICAT 2017
		Monitoren urineproductie onder niet operatieve omstandigheden	PREZIES 2017
	C-a3	Pre- or postoperative according (local) protocol	RICAT 2017, PREZIES 2017
	C-a4c	<ul style="list-style-type: none"> Assist in healing of open sacral or perineal wounds in patients with urinary incontinence 	RICAT 2017, PREZIES 2017
	C-a5	Continuous bladder irrigation for hematuria	RICAT 2017, PREZIES 2017
		Toediening van medicatie in de blaas	PREZIES 2017
	C-a6	Palliative care for terminally ill	RICAT 2017, PREZIES 2017
Inappropriate	C-a7c	<ul style="list-style-type: none"> Measuring volume of urine output aim for diagnostics (24 h urine), which cannot be assessed by other collection strategies, i.e. when patients are able to urinate by themselves 	RICAT 2017
		Other appropriate indication	PREZIES 2017
	C-i1	Incontinence with no open perianal or sacral wound	PREZIES 2017
	C-i2	Prevention of decubitus	PREZIES 2017
		Per-, postoperative use, duration not according to protocol	PREZIES 2017
	C-i3	Residubepaling	PREZIES 2017

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	C-i4	All not listed indications are defined as inappropriate	RICAT 2017
	C-i5	Measuring output when patients are able to urinate by themselves;	RICAT 2017
Unknown	C-u	Unknown indication	PREZIES 2017, RICAT 2017

* *a: appropriate indication*

i: inappropriate indication

c: critical indication, only valid in combination with another factor

u: unknown

2.2 Product

-

2.3 Methods

Table 2: Literature incorporated in the Catheter Check application model

	Literature	paper
<i>Include?</i>	<i>Theory or concept</i>	<i>under</i>
<i>Included</i>	Hibbard's patient engagement theory	Engagement
<i>Included</i>	PREZI & RICAT protocols	In addition, incorporated
<i>Included</i>	Wilde & Garvin's model of the concept 'self-monitoring'	
<i>Included</i>	Stiggelbout's Shared Decision Making model	Shared decision making
<i>Included</i>	Wildenbros' recommendations	Heuristics
<i>Included</i>	Horsky's Interface design principles	Heuristics
<i>Included</i>	Middleton's fourteen usability principles for the design of electronic medical records	Heuristics
<i>Included</i>	Fagerlin's recommendations for risk communication	Heuristics
<i>Not included</i>	Delone & McLean model of information system success	Successful mHealth
<i>Not Included</i>	Gemert-Peijnen's Holistic Framework to Improve the Uptake and Impact of eHealth Technologies	Successful mHealth
<i>Not included</i>	IMS Institute for Healthcare Informatics seven functionality categories	

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<i>Not included</i>	!!!Coulter's Model Development Process for Decision Aids	Development process
<i>Not included</i>	Sørensen's health literacy model	
<i>Not included</i>	Davis' Technology Acceptance Model	
<i>Not included</i>	Fallman's triangle model of interaction design research	

Table 3: Evaluations

Evaluation	Type	Measuring instruments
Evaluation 1	Contextual Inquiry	Literature research, interview audio transcriptions
Evaluation 2	Task completion and usability	Video recording of user evaluation, concurrent probing technique, SUS-questionnaire, application specific questionnaire, heuristics evaluation
Evaluation 3	Qualitative description of usability issues	Video recording of user evaluation, observation, verbalization

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Table 4: Data analysis

Instrument	Data analysis
Contextual inquiry	Stakeholder values, user needs Usability issues, task analysis
Usability evaluation (recordings, transcriptions)	
Interviews	Barriers
Questionnaires	Demographic information, user characteristics & percentages
mHealth heuristics	Usability solutions

Table 5: MoSCoW method

Prioritization category	Description
Must have	fundamental requirements without which the system will be unworkable and useless, effectively the minimum usable subset
Should have	would be essential if more time were available, but the system will be useful and usable without them
Could have	of lesser importance, therefore can more easily be left out of the current development
Want to have but Won't have this time round	can wait till a later development
*adapted from Benyon[33][33]	

2.4 Results

Table 6: Proposed Solutions

	Heuristics reference	Category	Proposed solution
1	4.1.1.2	readability	Increase min. font size of text to 14p.
2	4.1.1.1	readability	Use black text instead of grey.
3	2.2.1.	comprehension, interpretation	Support instructions with images.
4	1.3.2., 1.15.2	use of language	Match phrasing with user context and department.
5	1.16.	interpretation	Two-factor indications should be asked in two questions.
6	1.16.4	interpretation	Remove 'ik weet het niet' option for question 3.
7	1.10.4, 1.14.1, 1.16.2	navigation, interpretation	Replace 'lees instructies' and 'to do' labels by 'volgende'.
8	1.16.5.	use of language	Remove typing error.
9	1.10.9.	instructions	Include information relevant for decision making.
10	2.5.1	navigation, instructions quality	Show all information necessary for decision making, limit use of 'more info' feature/
11	3.5.2.	navigation	Provide ability to skip instructions.
12	1.6.1.	interpretation, instructions	Include risk information communication.
13	4.1.1.5.	interpretation, visibility	Use difference in background colour to group categories.
14	1.14.2, 2.1.8.	navigation, functional	On returning to main menu, answers should be saved until the next day.
15	1.12.5, 1.17.2, 2.8.1., 2.10.1	navigation, data entry	Overview screen should provide possibility to correct questions without going back.
16	2.1.3, 2.1.4	interpretation	The system should provide feedback during questionnaire.
17	2.1.7	feedback	Include motivational feedback.
18		feedback	Provide feedback on end and start of tasks.
19	1.2.1.	comprehension	Add icon to 'more information' option.
20	1.3.1, 1.12.5., 3.5.3.	navigation	Lock buttons for navigation at bottom of screen.

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Table 7: Outcome task analysis

a: outcome task analysis

	Sub category	Value to be measured	Measuring Instrument	Current level	Target level	Observed results											
						1a (n=6)		1b (n=5)		2a (n=6)		2b (n=6)		3a (n=5)		3b (n=6)	
						%	resp	%	resp	%	resp	%	resp	%	resp	%	resp
System quality	Task completion	Task completion: succesfull	observation	-	100%	50	3	100	5	100	6	80	4	80	4	100	6
		Task completion: not succesfull	observation	-	0%	50	3	0	0	0	0	20	1	20	1	0	0

b: outcome task analysis after correction

System quality	Task completion	Task	observation	-	100%	(n=6)		(n=5)		(n=6)		(n=5)		(n=4)		(n=6)	
						%	resp	%	resp	%	resp	%	resp	%	resp	%	resp
		Task completion: succesfull				50	3	100	5	100	6	100	4	100	4	100	6
		Task completion: not succesfull			0%	50	3	0	0	0	0	0	0	100	0	0	0

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Table 8: Usability Issues F1

	Category	Description of usability issue	N issues	N =6	Severity
System quality	Easy to manage (-) (1 issue, n=1)	Unsure how to continue and clicks in the middle of the overview screen	1	1	-
	Legibility (-) (2 issues, n=2)	Text too small	2	2	-
	Comprehensiveness (-)	Initial faulty interpretation of question	1	1	S
Content quality		Increased waiting time for question 4	1	1	-
		Question 4 is ambiguous	2	1	-
		Increased waiting time for question 5B	1	1	-
		Question 6A is ambiguous: double negation	2	2	-
		Increased waiting time for question 6A	2	2	-
		Does not know the answer to question 6A	1	1	-
		Wrong answer to question 7	2	2	-
		Does not know the answer to question 8	1	1	-
		Increased waiting time at overview screen	1	1	-
	Consistency (-)	Typo in question 6A: word repetition	1	1	-
	Persuasiveness (-)	‘Meer info’ is not used	4	4	-
		None of the users tapped the medical definition.	4	4	-
	Responsive (-)	Prototype cannot be displayed	1	1	S
Service quality		After pressing ‘Next’ button, the next question is not displayed	1	1	S
		Skipped question 5B	1	1	-
		‘Voltooi’ button after question 8 does not work			S

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.....	After clicking the 'Voltooi' button, the screen does not change	3	2	-
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Table 9: Usability Issues F2

A: prototype A

	Category	Measurement		Statement	N statements	N =6	Severity
System quality	User friendly (-)	Probe: summary	-	Cannot correct wrong answer to a question	1	1	-
		Probe: summary	-	Unclear that you can continue after the summary screen	2	1	S
		Probe: help	-	I think I would need help for using this application because of the letter size	1	1	S
Content quality	Legibility (-)	Probe: readability	-	Text is too small	4	3	S
		Probe: readability	-	Text of instructions is too small	1	1	S
	Legibility (+)	Probe: readability	+	Text is readable	1	1	-
	Comprehensiveness (-)	Probe: phrasing	-	Phrasing of question 6a is strange	2	2	-
		Probe: amount of text	-	The amount of text is a lot to take in	1	1	-
		Probe: amount of text	-	In the end, it is clear, but I think people will quit due to the the amount of text	1	1	-
		Probe: amount of text	-	Too much information in the result screen	1	1	-
		Probe: navigation	-	At the overview screen it is unclear that you have reached the end	1	1	S
		Probe: navigation	-	The overview screen is unclear	1	1	-
	Comprehensiveness (+)	Probe: phrasing	+	The use of language is short and clear	1	1	-
		Probe: phrasing	+	Phrasing is short and clear	1	1	-
		Probe: phrasing	+	Phrasing is understandable	1	1	-
		Probe: instructions	+	Instructions are clear	2	2	-
	Persuasiveness (-)	observation	-	'Meer info' is not used	3	3	-
		observation	+	Clicks on medical definition	3	3	-
Service quality	Responsive (-)	observation	+	'Meer info' is used	1	1	-
		observation	-	Clickable medical definition is not used	1	1	-
		verbalization	-	Answers are not saved after the questionnaire is completed	1	1	S

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B: Prototype B

	Category	Measurement		Statement	N statements	N =6	Severity
System quality		observation	-	"read instructions" is not intuitive	2	2	-
		observation	-	"to do" is not intuitive	1	1	-
Content quality	Legibility (-)	Probe: readability	-	Text is still too small	2	2	S
	Legibility (+)	Probe: readability	+	Readability is fine	3	3	-
		Probe: readability	+	Text is readable	1	1	-
	Comprehensiveness (-)	Probe: phrasing	-	Denial in question 6a is difficult	1	1	-
		Probe: phrasing	-	Question 4 is difficult, two questions at once	2	2	-
		Probe: amount	-	Too much information in result screen	1	1	-
		Probe: content	-	First mentioning the risks can be frightening	1	1	-
		Probe: content	-	You can also have urinary tract infection because of other reasons	1	1	-
	Comprehensiveness (-)	Probe: phrasing	+	Phrasing is clear	2	2	-
		Probe: phrasing	+	Phrasing is better	1	1	-
		Probe: amount	+	The amount of information is fine	2	2	-
		Probe: amount	+	The amount of information is more user friendly	1	1	-
		Probe: content	+	Content is clear	3	3	-
		Probe: images	+	Very usefull, makes you click through faster	1	1	-
		Probe: images	+	Images make it more attractive	1	1	-
		Probe: images	+	Images are fine/clear	3	3	-
		Probe: images	+	Images make it more clear	1	1	-
		Probe: instructions	+	Instructions are fine/clear	3	3	-
		Probe: instructions	+	Instructions are usefull	1	1	-
		Probe: instructions	+	Feedback in between is pleasant	1	1	-
Service quality	Persuasiveness (-)	observation	-	'Meer info' is not used	5	5	-
		observation	-	user tries to swipe	1	1	-

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.....	observation	-	Buttons are not visible at the bottom of the screen	1	1	-
Persuasiveness (+)	observation	+	'Meer info' is used	1	1	-
	observation	+	Clickable medical definition is not used	6	6	-

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Table 10: Stakeholder needs

Stakeholder	Problem description	Scenario	How to solve problems (according to respective stakeholder)	Who are affected
Infection prevention organizations	HAI occurrence is too high	1	Evidence based infection prevention & control interventions.	Patients (mortality, morbidity, duration hospital stay), hospital (costs)
Hospitals	eHealth does not live up to its promises	2	Patient-centered design, holistic framework, eHealth heuristics, involve users early on in process, other research.	Hospitals (cost), customers (pay for development of digital tools that are ineffective), patients (no access, low usability/satisfaction)
Patients	Digital health is not reliable, untrustworthy	3	Combine with direct contact doctors/nurses	Doctors, nurses
Patients	Accessibility: some people experience barriers that exclude them from using mHealth at all. Acceptability refers to fitness for purpose in the context of use. It also covers personal preferences that contribute to users 'taking to' an artefact, or not (p. 80)." [33]		Make it less complicated, use simple language, readable text, adapt it to needs of older people.	
Patients	Usability problems; "Usability refers to the quality of the interaction in terms of parameters such as time taken to perform tasks, number of errors made and the time to become a competent user."		See results.	Hospital (more usability problems, means less effective technology), patients (affects acceptability, opinion towards technology)
Doctors and nurses	New technologies should not infringe authoritative power of medical staff members.		Provide disclaimer, information in app	

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Requirements

P₀ (n=6)

P₁ (n=8)

P₂ (n=7)

P₃ (n=8)

1. Literature + recommendations → requirements 1.0 → Mockup 1
2. Field test Mockup 1 → Analyse results & propose solutions → requirements 1.1 → Mockup 1.1A
3. Test proposed solutions: requirements 1.1 → Mockup 1.1A & Mockup 1.1B (for comparison)
- 4.

3.1. Study design

To answer the research question semi-structured interviews were performed, involving heuristics analysis and a usability evaluation. An overview of the study design is shown in figure x. The evaluations were performed during three stages of iterative development. During each phase the usability specifications were improved and the prototype was adjusted accordingly. Four phases were planned.

F0. In order to support prioritization on the importance of the usability issues a preliminary study with 6 participants was conducted. During this evaluation the first *prototype P1a* was tested.

F1. In order to assess the effect of the implemented features on the reported usability issues, a usability evaluation was conducted on 8 patients comparing *prototype P1b* to *prototype P2a*. Additionally, the participant sessions were moderated on predetermined usability items through concurrent probing.

F2. In order to assess the effect of the implemented features on the reported usability issues, a usability evaluation was conducted on 7 patients comparing *prototype P2b* to

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prototype P3a. Additionally, to the concurrent probing technique, participants also filled in a SUS-questionnaire.

F3. For the last user evaluation *prototype P3b* was used.

Usability component	Subcategory	Outcome measure	Measuring instrument
Effectiveness	Task completion	Successful completion of task	Observation
	Information structure problem	Number of encountered problems due to navigation structure or arrangement of information	Observation
	Information quality: incomprehensibility	Number of encountered problems due to incomprehensible information	Observation & verbalization
	Information quality: inaccuracy	Number of encountered problems due to inaccurate information	Verbalization
	Feature utilization	% of features used	Observation
Efficiency	Error rate	Number of mistakes	Observation
	Failure	Number of failed commands	Observation
Satisfaction	Satisfaction	SUS-questionnaire	SUS-score
	Design	Number of expressions related to design	Verbalization
	Content	Number of expressions related to content	Verbalization
	Features	Number of expressions related to features	Verbalization
	Motivation	% of users motivated to use	Questionnaire

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Indication		2009 Centers for Disease Control and Prevention guideline	RICAT 2017	PREZIES 2017
1.1	appropriate	Patient has acute urinary retention or bladder outlet obstruction	Acute urinary retention or bladder outlet obstruction (≥ 150 cc)	Groot urineresidu in de blaas/afvloedbelemmering
1.2	appropriate	Need for accurate measurements of urinary output in critically ill patients	Accurate measurements of urinary output in critically ill patients required for treatment	Monitoren urineproductie onder niet operatieve omstandigheden
1.3	appropriate	Perioperative use for selected surgical procedures: 1. Patients undergoing urologic or other surgery on contiguous structures of genitourinary tract 2. Anticipated prolonged surgery duration; catheters inserted for this reason should be removed in postanesthesia care unit 3. Patients anticipated to receive large-volume infusions or diuretics during surgery 4. Need for intraoperative monitoring of urinary output	Pre- or postoperative according (local) protocol	Operatief gebruik (per-, postoperatief), duur volgens eigen protocol
1.4	Orange		X (als 54l sander 1.1)	Neurogene (overloop) blaas
1.5	appropriate	To assist in healing of open sacral or perineal wounds in incontinent patients	Assist in healing of open sacral or perineal wounds in patients with urinary incontinence	Incontinentie in aanwezigheid open perianale of sacrale wond
1.6a	Orange		X (kan 54l sanders genoteerd)	Toediening van medicatie in de blaas

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1.6b	appropriate		Continuous bladder irrigation for hematuria	Blaasspoelen bij bloedingen
1.7	appropriate	To improve comfort for end-of-life care if needed	Palliative care for terminally ill if needed	Verzorging terminale patiënt
1.8	Orange		X (kan 551 sanders genoteerd)	Andere terechte indicatie
	Orange		Volume measurements of urine output aim for diagnostics (24 h urine), which cannot be assessed by other collection strategies	1.8?
	inappropriate		Patient requires prolonged immobilization; Acute pijn?	Niet terecht volgens PREZIES
2.1	Red	As a substitute for nursing care of the patient or resident with incontinence	x	Incontinentie zonder open perianale of sacrale wond;

Section break

Appendix 3: Evaluations

3.1 Instructions for user evaluations (performed in Dutch)

Components

- introduce yourself
- explain research: duration, goal.
- Ask permission recording
- Check patient characteristics
- practice think aloud method
- Start: open browser, go to link

(

Example Usability Test Session

Here is an example test session.

1. *The facilitator will welcome the participant and explain the test session, ask the participant to sign the release form, and ask any pre-test or demographic questions.*
2. *The facilitator explains thinking aloud and asks if the participant has any additional questions. The facilitator explains where to start.*
3. *The participant reads the task scenario aloud and begins working on the scenario while they think aloud.*
4. *The note-takers take notes of the participant's behaviors, comments, errors and completion (success or failure) on each task.*
5. *The session continues until all task scenarios are completed or time allotted has elapsed.*
6. *The facilitator either asks the end-of session subjective questions or sends them to an online survey, thanks the participant, gives the participant the agreed-on incentive, and escorts them from the testing environment.*

)

Text

(We gaan kijken naar de gebruiksvriendelijkheid. U kunt er gewoon doorheen klikken. Zeggen wat u er goed en slecht aan vindt op gebied van gebruiksvriendelijkheid.)

Appendix 3: Evaluations

3.2 Concurrent probing items

Table 11: Concurrent Probing Items

Type probe	Categorie (barriere)	Voorbeeld	Toelichting
Interpretation/ recall	Afbeeldingen (motivational issue)	I. Wat vindt u van de afbeeldingen?	a. Duidelijk b. Onduidelijk
Comprehension	Tekst (visuele barriere)	II. Wat vindt u van de leesbaarheid van de tekst? III. Wat vind u van de formulering van de tekst?	a. Verhelderend b. Verwarrend
Comprehension/ Interpretation	Instructies (motivational issue)	IV. Wat vond u van de instructies?	a. Makkelijk b. Moeilijk
Paraphrasing	Terminologie (cognitive barriers)	V. Wat vind u van het taalgebruik? VI. Medische termen begrijpelijk?	a. Kunt u betekenis eigen woorden omschrijven?
Specific: scripted	Navigatie (motivational issue)	VII. Wat vind u van de manier van invoeren? VIII. Hoe is het om fouten te verbeteren?	a. Makkelijk b. Moeilijk
Comprehension/ Interpretation	Feedback (cognitive barriers)	IX. Wat vind u van de hoeveelheid informatie? X. Wat vind u van de uitleg? XI. Wat vond u van de risico-informatie?	
Specific: scripted	Doel (motivational issue)	XII. Is het doel van de app duidelijk?	a. Zou u dat kunnen omschrijven?
General	Twijfel	“Ik zie dat u twijfelt. Vertellen wat er door u heengaat?”	

Sources:

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3771159/>
- <http://www.dea.univr.it/documenti/OccorrenzaIns/matdid/matdid823948.pdf>
- <https://www.usability.gov/get-involved/blog/2013/04/moderating-usability-tests.html>

Appendix 3: Evaluations

3.3 System Usability Scale (modified)

zeer mee zeer mee
oneens eens

1	Ik denk dat ik gemotiveerd zou zijn om de 'Katheter Check-module' te gebruiken.	1	2	3	4	5
2	Ik denk dat ik door de 'Katheter Check- module' meer bewust ben geworden over het belang van het tijdig verwijderen van een urinekatheter.	1	2	3	4	5
3	Ik denk dat ik door de 'Katheter Check- module' meer kennis/begrip heb van het risico op een urineweginfectie.	1	2	3	4	5
4	Ik denk dat ik door gebruik van de 'Katheter Check-module' meer geneigd/gemotiveerd zou zijn om bij te houden of een katheter nog nodig is voor mij.	1	2	3	4	5
5	Ik voel me door de 'Katheter Check- module' aangemoedigd om hulp te vragen voor het verwijderen van mijn urinekatheter (indien nodig).	1	2	3	4	5
6	Ik denk dat ik door de 'Katheter Check- module' vaker mijn arts/verpleegkundige zal vragen naar de noodzaak van mijn urinekatheter.	1	2	3	4	5
7	Ik denk dat ik door de 'Katheter Check- module' vaker mijn arts/verpleegkundige zal vragen naar de noodzaak van mijn urinekatheter.	1	2	3	4	5

Appendix 4: Prototype evaluation

Phase 1, Prototype Evaluation

Goals. In order to support prioritization on the importance of the usability issues a preliminary study with 6 participants was conducted. During this evaluation the first *prototype P1a* was tested.

Data Sources. Phase 1 of the prototype evaluation asked the patients to complete the CatheterCheck module and to express their thoughts out loud. The observations were recorded on video. This initial phase resulted in fifteen unique usability issues.

Phase I was conducted immediately after nursing staff confirmed inclusion criteria, and as a result throughout the evaluation sessions it was revealed that several patients experienced difficulties with using their smartphone due to side effects of their medication. Therefore, the results began to reveal a shift in the potential user group that excluded patients too ill or otherwise unable to use their smartphone as usual. Overall, all of the data proved valuable to the design process and matches the expectation that a mobile application would only be used by a subgroup of the catheterized patients.

Data Analysis. Incorporating the predefined prioritization method, three unique areas of emerging issues became apparent, and were matched with an appropriate model for evaluation referred to as Phase 1-Step A: system quality, content quality and service quality. Once these three categories were identified, the initial 15 issues from the field test participants were assigned to one of these categories.

Upon further examination of the results from Phase 1, and continual iterative application of the heuristics, the researchers found similarities and identified important issues, which led to the prioritization of required improvements resulting in 5 categories for improvement: readability, use of language, interpretation accuracy, navigation and goal clarity, which were referred to as Phase 1-Step B (to implement in Phase II). This

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prioritization of issues then drove the creation of categories for concurrent probing (Table 12).

Starting with the list of issues and observations from the evaluation of the preliminary prototype created by the researcher, the researchers reorganized the results from Step B, which resulted in a new selection of improvements referred to as Phase I-Step C. The resulting improvements were: the inclusion an additional instructions module and implementation of supporting illustrations. It is these resulting improvements that guided the design of the prototypes for Phase 2.

A method for the refinement and categorization was applied which lead to the following categorizations of improvements:

1. System functionality category
 - a. Compatibility with smartphone
 - b. Buttons
 - c. Data storage
 - d. Input methods
 - e. Navigation
2. Content quality category
 - a. Text comprehensibility
 - b. Interpretation accuracy
 - c. Information quantity
 - d. Goal clarity
3. Usability category
 - a. Task completion
 - b. Text readability
 - c. Appropriate context of use

Phase 2, Prototype Evaluation

Goals. In order to assess the effect of the implemented features on the reported usability issues, a usability evaluation was conducted on 8 patients comparing *prototype P1b* to *prototype P2a*. Additionally, the participant sessions were moderated on predetermined usability items through concurrent probing.

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Data Sources. Phase 2 involved A/B testing, a method to compare the effect of different features. Patients were asked to interact with two prototypes: an InVision Mockup prototype and a functional prototype, both designed after analysis of data acquired in Phase 1. Task completion was scored.

Data Analysis. Observations during the cooperative evaluation resulted in additional usability issues. These potential areas for improvement are being used as determining factors in the next iterative phase of design.

Phase 3, Prototype Evaluation

Goals. In order to assess the effect of the implemented features on the reported usability issues, a usability evaluation was conducted on 7 patients comparing *prototype P2b* to *prototype P3a*. Additionally, to the concurrent probing technique, participants also filled in a SUS-questionnaire.

Data Sources. Phase 3 involved several steps. First, Step 1- A/B testing, a method to compare the effect of different features. Patients were asked to interact with two prototypes: an InVision Mockup prototype and a functional prototype, both designed after analysis of data acquired in Phase 2. Second, Step 2 – patients were asked to fill in a questionnaire after using each prototype. The form included a System Usability Scale and a set of app specific questions adapted from the MARS-rating scale.

Data Analysis.

Phase 4, Prototype Evaluation

Goals. Final user validation of the app and the associated concepts to confirm the requirement specifications.

Data Sources. Phase 4 tested the final functional *Prototype P3b* in 5 participants.

Data Analysis. All participants achieved successful task completion.

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Appendix 5: Design Document

Appendix X7: Scenario

Conceptual scenario

Scenario name:

Scenario history

Scenario type:

Pact

People – patients, older adults, smartphone users

Activities – self-management, participating in healthcare decision making process, active health behaviour

Context – hospital environment, urinary catheter usage

Technology – mobile device (smartphone or tablet)

Rationale

This scenario was developed to further understand the problem situation and activities that are part of the existing system. It is intended to provide a rich description of the general context of the way in which patients engage in self-management activities. All the practical activities that are part of the system are explicitly mentioned to explore how they contribute to the patient experience. This scenario is also intended to provide a rich picture of the context to identify the various touch points of the system and their relation to the information space.

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Scenario

P1 P. is admitted to hospital.

P2 P. receives instructions from doctor.

P3 P. receives instructions from nurse about application

P4. P. downloads app and sets surgery date

P4 P. is taken out for surgery

P5 P. is dull from medication

P6 P. decides to use app to check catheter usage.

P7 P. completes the checklist and reads the result